DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

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95397d

WARNING LETTER

NWE-19- 02W

June 24, 2002

VIA FEDEX

Michael J. McNaboe, President
Vision Laboratories DBA
VisionTel Communications LLC
51 Dow Highway, Suite 11
Eliot, Maine 03903

Dear Mr. McNaboe:

This letter is written in reference to the marketing of "Epiclear Liposomal Facial Remedy" by your firm. The product labeling and promotional literature indicate that the product is for over-the-counter (OTC) treatment of acne. According to labeling and promotional literature, the product contains water, glycerol, phosphatidylcholine from natural lecithin, vitamin C, ethanol, vitamin E-acetate, menthol, vitamin A-palmitate, and chlorhexidine-salt as ingredients.

Your "Epiclear Liposomal Facial Remedy" package insert "INSTRUCTIONS FOR USE" states "For the first 3 days, spray epiclear onto affected area 4 to 5 times a day (use 8 times a day if you have large, red pimples), and rub liquid gently into skin with fingertips." Also, the package insert states "Continue using epiclear twice a day, every other day until blemishes have disappeared and skin has healed." Other promotional literature entitled "Epiclear Amazing new all-natural formula" for your product states "Do you suffer with acne or other skin irritations..." and "Unique and highly effective, epiclear is specially designed to penetrate deeply into your pores, unclogging and killing the bacteria that cause pimples, blackheads, whiteheads, and patches of redness."

Based on the intended uses established by the claims cited above, the product is a drug as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

As labeled and promoted "Epiclear Liposomal Facial Remedy" is subject to the acne final regulations found in 21 CFR 333.301, 333.310, 333.320, and 333.350. Although the active ingredients in this product are not specifically identified on the product label, labeling distributed with the product promote the ingredients in the formula for acne treatment. None of these ingredients are permitted as active ingredients under the regulations for OTC acne products. Because the labeling and formulation of "Epiclear Liposomal Facial Remedy" do not comply with the final regulations, your product is a "new drug" (Section 201(p) of the Act) which may not be legally marketed in the United States without an approved New Drug Application (Section 505).

The product is misbranded (Sections 502(f)(1) and 502(f)(2) of the Act) for failure to comply with the final regulations covering topical acne products under 21 CFR Parts 333.301 with respect to directions for use and required warnings.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days of receipt of this letter and the specific steps you have taken to correct the violations described above. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be implemented.

You should direct your reply to Bruce R. Ota, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Mr. Ota at 781-596-7762.

Sincerely,

Gail T. Costello
District Director
New England District Office